DETAILED ACTION

Formal matters

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 25, 2008 has been entered.

3. Claims 21, 23-27 and 41-44 are pending in the instant patent application.

Claims 21, 23-27 and 41-44 are under examination in the instant office action.

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed on March 25, 2008 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 21, 23-27 and 41-44 stand rejected under 35 U.S.C. 102(e) as being anticipated by Sims et al. (US Patent 6, 555, 520, April 29, 2003, filed May 9, 2001) as evidenced by Bost et al. (Immunol. Invest. 1988; 17:577-586) and Bendayan et al. (J. Histochem. Cytochem. 1995; 43:881-886) for those reasons of record in section 4 of Paper mailed on October 10, 2007.

Applicant traverses the rejection essentially based on the premise that "because the 60/101,318 provisional application ("the '318 provisional application") allegedly fails to disclose a specific, substantial and credible utility for the claimed invention, the claimed invention does not have priority to the '318 provisional application" (p. 2 of the Response). Applicant further argues that the utility of the instant claimed antibodies to IL-B50 is based on the specific and substantial credible utility of the antigen itself, the IL-B50 polypeptide (p. 3 of the Response) and that '318 application fully discloses that utility. Applicant's arguments have been fully considered but are not persuasive for the following reasons.

As fully explained in the previous office actions of record, the similarity between the instant IL-B50 and IL-7 is significant only in terms of mathematical statistical analysis. The amino acid sequences of the instant IL-B50 encoded by SEQ ID NO: 1 and the known sequence of IL-7 are similar only by about a quarter of the sequence length (28.1%), which means that 71.9% of the sequence of IL-B50 bears no resemblance to IL-7. The Examiner maintains that the

instant specification fails to present any factual evidence or sound scientific reasoning to support a conclusion that molecules that have almost no common structure (28.1%) would have a common function and this function would be related to the effect on hematopoietic cells. There is no identification of a specific common structure that is known to be particularly associated with the function at the time of filing. All that is disclosed in the '318 application is the structure of IL-B50 polypeptide.

Further, the '318 provisional application clearly states that IL-B50 polypeptides are expected to have either inhibitory or stimulatory effect on hematopoietic cells, which clearly does not meet the requirement of 35 USC § 112, first paragraph, for not providing an enabled disclosure in return for the award of the priority of the effective filing date. Granted, those skilled in the art could screen IL-B50 polypeptides to identify for themselves their specific effect on hematopoietic cells. That, however, does not make up for the deficiency of the specification's enablement.

At p. 4 of the Response, Applicant refers to non-precedential opinion by the Board of patent appeals and Interferences to support the argument regarding the utility rejection. Applicant is reminded that Rule 47.6 specifically prohibits the citation of non-precedential opinions, and therefore Applicant's argument is unavailing.

The Declaration of Andrej Sali under 37 CFR 1.132 filed on January 10, 2007 is insufficient to overcome the rejection of claims 21, 23-27 and 41-44 based upon 102(e) as set forth in the last Office action for reasons set forth below.

The declaration of Dr. Sali states that the structural sequence similarity between IL-7 and the instant claimed IL-B50 is statistically significant and based on that statistically significant

similarity, he "would have believed that IL-B50 would have had functions similar to functions known to be associated with IL-7, including in particular the specific function of stimulating T cells and B cells" (section 4). Thus, the Declaration provides only Dr. Sali's own conclusions and no references to scientific reasoning or any other evidentiary support (see *Meitzner v. Mindick,* 549 F.2d. 775, 782, 193 USPQ 17, 22 (CCPA 1977), "Argument of counsel cannot take the place of evidence lacking in the record"). It is important to point out that the Examiner has never disputed that the similarity between IL-7 and IL- B50 is of statistical significance; the issue at hand here is that the similarity between these molecules is only 28.1%. The instant specification, Applicant's arguments and both of Dr. Sali's Declarations fail to present any evidence, reference to prior art or a single line of scientific reasoning to support a conclusion that the disclosed protein would have a certain specific, for example "stimulatory effect", on cells, which would support its immediate usefulness for the public. The Examiner maintains that in order to discover how to use the instant polypeptides and antibodies that bind to it, a skilled practitioner would have to perform a significant amount of further research to discover what is, if any that particular effect that IL-B50 shares with IL-7. Thus, at the time of filing, to employ the antibodies to IL-B50 of the instant invention in any of the disclosed methods would clearly be using it as the object of further research which has been determined by the courts to be a utility which, alone, does not support patentability.

Thus, in the instant case, characterization of the claimed polypeptide as having 28.1% structural similarity to the known polypeptide with diverse spectrum of functions and assertion that it would probably either inhibit or stimulate the activity of certain cell types (provisional application filed in 1998 states that "[i]t is likely that IL-B50 has either stimulatory or inhibitory

effects on hematopoietic cells") is clearly not sufficient to support the practical utility of the antibodies that bind to IL-B50 as immediately available for public benefit.

Therefore, because the instant invention is only fully enabled in the instant specification, the effective filing date of the instant invention is awarded as the filing date of the instant application, which makes Sims et al. document a proper prior art under 102(e).

Conclusion

8. No claim is allowed.

9. This is a request for continued examination of applicant's earlier Application No. 10/601,105. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

10. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

June 3, 2008

/Olga N. Chernyshev, Ph.D./
Primary Examiner, Art Unit 1649